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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,568	10/08/2003	Patrick Miles	029US1	1741
30328	7590	03/31/2010	EXAMINER	
NuVasive c/o CPA Global P.O. Box 52050 Minneapolis, MN 55402			NGUYEN, VI X	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,568	Applicant(s) MILES ET AL.	
	Examiner Victor X. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-60 is/are rejected.
- 7) ☒ Claim(s) 61-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/11/2010</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

1. This action is in response to the amendments received on 8/6/2009.

In response to applicant's remarks of 8/6/2009, the examiner has removed all prior 35 USC, first paragraph and specification objections.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-21,23-51,53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al (5,728,046) in view of Gharib et al (US 2005/0075578). Mayer discloses a method of distracting and retracting tissue to provide a corridor to operate on vertebra. Mayer's retractor has a plurality of blades 7 and 18 which are movable apart from each other and extend in a direction laterally from an incision depending on how it is inserted. However, Mayer is silent regarding a first retractor blade is positioned along a posterior aspect of the spinal target side via a lateral, trans-psoas approach.

Gharib teaches a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, including a first retractor blade, fig. 2, element 62 introduced to the spinal target site via a lateral trans-psoas approach where the first retractor blade is positioned along a posterior aspect of the spinal target site (see paragraph 62 and 64). It would have been obvious to one having ordinary skill in the art at the same time the

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invention was made to modify Mayer by incorporating the step of accessing a spinal target site via a lateral, trans-psoas surgical approach as taught by Gharib in order to establish an operative corridor to an intervertebral target site in a posterior lateral, trans-psoas fashion so as to avoid the bony posterior element of the spinal column. *Gharib also discloses the invention substantially as recited in claims 54-59 which includes the stimulation electrodes on the k-wire, retractor blades and the control unit and display (see paragraph 60, 62 and 92).*

Claims 22,37 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al in view of Gharib et al as applied to claims 20,35 and 50 above and further in view of Slotman et al 5,599,279.

Mayer et al in view of Gharib et al discloses the invention substantially as claimed.

Mayer et al in view of Gharib is silent regarding a retractor has two dilator members inside of an outer cannula. However, Slotman discloses a vertebral retractor having two movable dilator or retractor members inside an outer cannula (see figures. 5,7,11 and 13).

It would have been obvious to have provided the spreading device of Slotman together with the device of Mayer et al in view of Gharib and put them together in a kit or use them together in a procedure, as both instruments find use in the same type of procedures.

Allowable Subject Matter

3. Claims 61-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The following is a statement of reasons for the indication of allowable subject matter:

Claims 61-63 contain allowable subject matter, in particular, the step of determining at least one of nerve proximity and nerve direction includes determining a threshold stimulation level required to evoke said neuromuscular response and wherein said step of determining a threshold stimulation level includes establishing first a bracket containing said threshold stimulation level and bisecting said bracket to form a smaller second bracket containing said threshold stimulation level.

Response to Arguments

4. Applicant's arguments filed 8/6/2009 have been fully considered but they are not persuasive.

With regard to the combination applied to the claims, applicants argue that Mayer does not disclose the step of fixing a first retractor blade introduced by a lateral trans-psoas approach such that the first blade is positioned along a posterior aspect of the spinal target and Gharib does not overcome the voids in the teachings of Mayer. Examiner disagrees. In fact, as seen in fig. 2 of Mayer does disclose a plurality of retractor blades 7, 17, 19. A person skill in the art would have looked at fig. 2 of Mayer from the view point such as fig. 2 can be rotated to the right side. A surgeon will have fig. 2 procedure which approaches from the posterior aspect of the spinal target site such that the first retractor blade 7 is relatively fixed and is positioned along a posterior aspect of the spinal target side. The examiner clearly stated in the rejection that Gharib teaches a method of accessing a spinal target site via a lateral, trans-psoas surgical approach, including a first retractor blade, fig. 2, element 62 introduced to the spinal target site via a lateral trans-psoas approach where the first retractor blade is positioned along a posterior aspect of the

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spinal target site (see paragraph 62 and 64). It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Mayer by incorporating the step of accessing a spinal target site via a lateral, trans-psoas surgical approach as taught by Gharib in order to establish an operative corridor to an intervertebral target site in a posterior lateral, trans-psoas fashion so as to avoid the bony posterior element of the spinal column.

Further, applicants state that there were no rejections which were set forth regarding to claims 54-59. Examiner disagrees. In fact, on page 4, lines 12-14 of the Office action mailed on 3/5/2009 did address the rejections of claims 54-59. Therefore, the rejection of claims 54-59 also stand.

Accordingly, the above noted references are still considered to read on the claimed limitations of the claims noted.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699.

The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VN /

Examiner, Art Unit 3731

3/28/2010

/Gary Jackson/

Supervisory Patent Trainer

TC 3700

March 28, 2010